PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant:	Ruchika Singhal, Robert M. Skime and Carl D. Wahlstrand	Confirmation No.	6697
Serial No.:	10/731,868		
Filed:	December 09, 2003	Customer No.:	28863
Examiner:	William H. Matthews	Group Art Unit:	3774
Docket No.:	1023-330US01		
Title:	IMPLANTATION OF LOW-PROFILE IMPLANTABLE MEDICAL DEVICE		

CERTIFICATE UNDER 37 CFR 1.8 I hereby certify that this correspondence is being transmitted via the United States Patent and Trademark Office electronic filing system on September 3, 2009.

By: /Patricia Cygan/
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APPEAL BRIEF

Mail Stop: Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is an Appeal from the final Office Action mailed March 31, 2009 and the Advisory Action mailed June 17, 2009. Appellant filed a Notice of Appeal on June 30, 2009. Accordingly, the due date for this appeal brief, with the filing of a Request for Extension of One Month is September 30, 2009.

Please charge Deposit Account No. 50-1778 in the amount of $540.00 for Appellant's appeal brief fee, as required by 37 C.F.R. §41.37(a)(2).

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REAL PARTY IN INTEREST

The real party in interest is Medtronic, Inc. of Minneapolis, Minnesota, the assignee of record.

RELATED APPEALS AND INTERFERENCES

There are no known appeals or interferences related to this matter.

STATUS OF CLAIMS

Claims 1–7, 9–12, 15–17 and 24–32 are on appeal in this case.

Claims 12 and 27 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement and the enablement requirement.

Claims 1–7, 9–12, 15–17 and 24–32 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Pat. No. 6,427,086 to Fischell et al. (hereinafter "Fischell") in view of U.S. Pat. No. 6,648,914 to Berrang et al. (hereinafter "Berrang") and U.S. Pub. No. 2003/0109903 Berrang et al. (hereinafter "Berrang Application").

Claims 13 and 14 are withdrawn and are not on appeal. In addition, claims 8 and 18–23 are cancelled and not on appeal.

STATUS OF AMENDMENTS

The claims on appeal are those submitted in the Amendment filed on July 17, 2008 in response to the final Office Action mailed April 17, 2008. This Amendment was entered by the Examiner in conjunction with the Office Action mailed September 18, 2008.

SUMMARY OF CLAIMED SUBJECT MATTER

Appellant's invention relates to techniques for implantation of a low-profile implantable medical device (IMD) between the scalp and the skull of a patient. The claims on appeal include three independent claims: claims 1, 26 and 28. The independent claims are each directed to methods.[1] Claims 2–7, 9–12, 15–17, 24, 25, 30 and 31 are dependent on independent claim 1,

[1] *See* claims 1, 26 and 28.

claims 27 is dependent on independent claim 26, and claims 29 and 32 are dependent on independent claim 28.[2]

Appellant's invention as recited by claim 1 is directed to a method comprising making an incision in a scalp of a head of a patient to create a scalp flap;[3] and separating the scalp flap from a skull of the patient.[4] The separated scalp flap is attached to the remainder of the scalp by a fold.[5] The method further comprises, after separating the scalp flap from the skull, separating a portion of the remainder of the scalp adjacent to the fold from the skull to create a pocket adjacent to the fold and between the scalp and the skull;[6] placing at least a portion of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp;[7] drilling one or more burr holes in a portion of the skull of the patient exposed by separating the scalp flap from the skull;[8] and inserting one or more leads through the burr holes and into a brain of the patient.[9]

Appellant's invention as recited by claim 26 is directed to a method comprising making an incision in a scalp at a top of a head of a patient to create a scalp flap at the top of the head of the patient;[10] and separating the scalp flap from a skull of the patient.[11] The separated scalp flap is attached to the remainder of the scalp by a fold.[12] The method further comprises, after separating the scalp flap from the skull, separating a portion of the remainder of the scalp adjacent to the fold from the skull to create a pocket adjacent to the fold and between the scalp and the skull;[13] placing at least a portion of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp;[14] drilling one or more burr holes in a portion of the skull of the patient exposed by separating the scalp flap from the skull;[15] inserting

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[2] *See* claims 1–7, 9–12, 15–17 and 24–32.
[3] Specification, paragraph [0021] and Figure 2.
[4] Specification, paragraph [0021] and Figure 3.
[5] Specification, paragraph [0022], line 5.
[6] Specification, paragraph [0022] and Figure 4.
[7] Specification, paragraph [0022] and Figure 4.
[8] Specification, paragraph [0021] and Figure 3.
[9] Specification, paragraph [0022] and Figure 4.
[10] Specification, paragraph [0021] and Figure 2.
[11] Specification, paragraph [0021] and Figure 3.
[12] Specification, paragraph [0022], line 5.
[13] Specification, paragraph [0022] and Figure 4.
[14] Specification, paragraph [0022] and Figure 4.
[15] Specification, paragraph [0021] and Figure 3.

one or more leads through the burr holes and into a brain of the patient;[16] connecting the one or more leads to the low-profile implantable medical device;[17] covering the low-profile implantable medical device, leads and burr holes with the scalp flap; and closing the incision.[18]

Appellant's invention as recited by claim 28 is directed to a method comprising making an incision in a scalp at a top of a head of a patient to create a scalp flap at the top of the head of the patient;[19] and separating the scalp flap from a skull of the patient.[20] The separated scalp flap is attached to the remainder of the scalp by a fold.[21] The method further comprises, after separating the scalp flap from the skull, separating a portion of the remainder of the scalp adjacent to the fold from the skull to create a pocket adjacent to the fold and between the scalp and the skull;[22] and placing at least a portion of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp.[23]

[16] Specification, paragraph [0022] and Figure 4.
[17] Specification, paragraph [0022] and Figure 4.
[18] Specification, paragraph [0022] and Figure 4.
[19] Specification, paragraph [0021] and Figure 2.
[20] Specification, paragraph [0021] and Figure 3.
[21] Specification, paragraph [0022], line 5.
[22] Specification, paragraph [0022] and Figure 4.
[23] Specification, paragraph [0022] and Figure 4.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Appellant submits the following ground of rejection to be reviewed on Appeal:

(1) The rejection of claims 12 and 27 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement.

(2) The rejection of claims 12 and 27 under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement.

(3) The rejection of claims 1–7, 9–12, 15–17 and 24–32 under 35 U.S.C. § 103(a) as being unpatentable over Fischell in view of Berrang and Berrang Application.

ARGUMENT

Appellant respectfully traverses the current rejections advanced in the final Office Action mailed March 31, 2009 and the Advisory Action mailed June 17, 2009 and requests reversal by the Board of Patent Appeals based on the arguments below. Appellant respectfully requests separate review of each set of claims argued under separate headings.

The Supreme Court recently elaborated on the standard of obviousness under 35 U.S.C. § 103(a) in *KSR Int'l Co. v. Teleflex, Inc.*[24] As reiterated by the Supreme Court in *KSR*,[25] the framework for the objective analysis for determining obviousness under 35 U.S.C. § 103 is stated in *Graham* v. *John Deere Co.*[26] Obviousness is a question of law based on underlying factual inquiries. The factual inquiries enunciated by the Court are as follows:

(1) Determining the scope and content of the prior art;

(2) Ascertaining the differences between the claimed invention and the prior art; and

(3) Resolving the level of ordinary skill in the pertinent art.

In *KSR*, the Supreme Court explained that the Examiner must identify a logical reason why a person of ordinary skill in the art would have been led to make a modification or combination to arrive at the claimed invention. An invention composed of several elements is not proved obvious merely by demonstrating that each of the elements was independently known.[27]

Consistent with *KSR*, the Federal Circuit has stated that there must be "some rationale, articulation, or reasoned basis" to support the legal conclusion of obviousness."[28] The reason for modification need not conform to the particular motivation or objective of the patent Appellant.[29] However, there still must be some need or problem known in the art that would have provided a reason for combining elements in the manner claimed.[30]

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[24] 550 U.S. 398, 82 USPQ2d 1385 (2007).
[25] *KSR*, 82 USPQ2d at 1388.
[26] 383 U.S. 1, 148 USPQ 459 (1966).
[27] *KSR*, 82 USPQ2d at 1389.
[28] *Alza Corp. v. Mylan Laboratories*, 80 USPQ2d 1001, 1005 (Fed. Cir. 2006) (citing *In re Kahn*, 78 USPQ2d 1329 (Fed. Cir. 2006)).
[29] *KSR*, 82 USPQ2d at 1389-90.
[30] *Id.*

Furthermore, a basic premise of the obviousness analysis set forth in *KSR* is that the combination of prior art references must actually disclose the elements recited in the claims. Consistent with this premise, the Manual for Patenting Examining Procedure (MPEP) sets forth three basic requirements to an obviousness analysis as follows. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.[31]

The *KSR* case clarified that the "suggestion or motivation" requirement is more broadly a requirement that the Examiner articulate a "rational reason" for the modification. However, the *KSR* case did not modify the basic requirement of the obviousness analysis that requires the Examiner to show that the prior art collectively teaches the elements of Appellant's claims. Accordingly, if Appellant can show that the prior art lacks a teaching of one or more elements of the pending claims, the obviousness rejections must be reversed. In addition, if there is no *rational* reason a person of ordinary skill in the art would have arrived at the claimed invention in view of the prior art, the obviousness rejections must be reversed.

In addition to novelty and nonobviousness, the claimed invention must have adequate support in the disclosure as originally filed to comply with the written description requirement of 35 U.S.C. § 112, first paragraph. The proscription against the introduction of new matter in a patent application serves to prevent an Appellant from adding information that goes beyond the subject matter originally filed.[32] There is no *in haec verba* requirement, and added claim limitations may be expressly, implicitly, or inherently supported in the originally filed disclosure.[33] The Examiner has the initial burden of presenting by a preponderance of evidence why a person of ordinary skill in the art would not recognize in an Appellant's disclosure a description of the invention defined by the claims.[34]

"[T]he 'essential goal' of the description of the invention requirement is to clearly convey . . . that an appellant has invented the subject matter which is claimed."[35] Consistent with this

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[31] *See* MPEP 2143.
[32] 35 U.S.C. § 132 and 35 U.S.C. § 251.
[33] *In re Oda*, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971).
[34] *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976).
[35] *In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977).

goal, the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species.[36] As an example, in *In re Smythe*, the CCPA found that the phrase "air or other gas which is inert to the liquid" was sufficient to support a claim to "inert fluid media" because the description of the properties and functions of the air or other gas segmentizing medium would suggest to a person of ordinary skill in the art that appellant's invention includes the use of "inert fluid" broadly.[37]

As represented by the decision of *In re Smythe*, it is not necessary that the specification as originally filed includes *in haec verba* recitation of a limitation used to represent a genus of a disclosed species. Instead, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those of ordinary skill in the art that, as of the filing date sought, Appellant was in possession of the invention as now claimed.[38]

Furthermore, 35 U.S.C. § 112, first paragraph also provides a requirement that the claimed invention is enabled as of the filing date of the application.[39] The test of enablement requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention.[40] Determining enablement is a question of law based on underlying factual findings.[41]

The Supreme Court set forth the standard for enablement in *Mineral Separation v. Hyde* by posturing the question, "is the experimentation needed to practice the invention undue or unreasonable?"[42] Even though the statute does not use the term "undue experimentation," the Federal Circuit has interpreted the enablement requirement set forth in 35 U.S.C. § 112, first paragraph to require that the claimed invention be enabled so that any person skilled in the pertinent art can make and use the invention without undue experimentation.[43] However, a patent need not teach, and preferably omits, what is well known in the art.[44] In addition, any part of the specification can support an enabling

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[36] MPEP 2163.05.
[37] 480 F.2d 1376, 1383, 178 USPQ 279, 285 (CCPA 1973).
[38] *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991).
[39] *Chiron Corp. v. Genentech Inc.*, 363 F.3d 1247, 1254, 70 USPQ2d 1321, 1325-26 (Fed. Cir. 2004); see also MPEP 2164.05(a).
[40] MPEP 2164.01.
[41] *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991); *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984).
[42] 242 U.S. 261, 270 (1916).
[43] *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988).
[44] *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987);

disclosure, even a background section that discusses, or even disparages, the subject matter disclosed therein.[45]

FIRST GROUND OF REJECTION UNDER APPEAL

In the Office Action, the Examiner rejected claims 12 and 27 under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. Appellant respectfully request that the Board reverse this rejection. Appellant's specification as filed conveys that Appellant had possession of the invention as recited in the claims.

GROUP 1 - (Claims 12 and 27)

Claim 12 recites the method of claim 1, further comprising creating a recess in the skull; and placing the low-profile implantable medical device in the recess. Claim 27 recites the same features, but is dependent on independent claim 26.

In the Office Action, the Examiner argued that the Appellant's specification does not provide support for the combination of using a pocket (as recited in independent claims 1 and 26) and a recess (as recited in claims 12 and 27).[46] Appellant respectfully disagrees.

Support for the feature of creating a recess is provided by both paragraph [0051] and claim 12 of the application as filed. The Office Action argued that paragraph [0051] merely provides an alternative method of implantation to the creation of a pocket.[47] However, the context of paragraph [0051] within Appellant's specification as filed provides support for the combination of placing an IMD within a pocket and a recess.

As stated in paragraph [0046] of Appellant's specification as filed, "[i]n some cases, implantation of an IMD may include an extra surgical stage." The Office Action argued that this extra surgical stage can only be the use of a dummy IMD. Appellant notes that creation of a

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and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).

[45] *Callicrate v. Wadsworth Mfg., Inc.*, 427 F.3d 1361, 77 USPQ2d 1041 (Fed. Cir. 2005)(discussion of problems with a prior art feature does not mean that one of ordinary skill in the art would not know how to make and use this feature).

[46] Final Office Action dated March 31, 2009, page 2.

[47] Final Office Action dated March 31, 2009, page 2.

recess may not even constitute an extra surgical stage as it may be performed during a single surgery as part of the implantation of an IMD. In any event, following the discussion of the use of a dummy IMD in paragraphs [0046]-[0050], paragraph [0051] states in part, "In addition, the surgeon may in some cases determine that the skull of the patient may be prepared to receive the IMD. The surgeon may, for example, create one or more troughs or recesses in the skull of the patient to receive the IMD or one or more modules thereof." (Emphasis added.) Absent any intrinsic evidence to the contrary, one of ordinary skill in the art would expect from the context of Appellant's specification, and particularly the indication that the technique is "in addition" to the other techniques, that formation of a recess can be combined with the other techniques previously described in Appellant's specification, including creating a pocket. The Examiner did not provide any reason to overcome the language in Appellant's specification that would allow formation of a recess to be combined with the techniques previously described in Appellant's specification.

For example, while Appellant does not acquiesce that Appellant's specification as filed does not provide written description support for a recess beneath a pocket, Appellant notes that claims 12 and 27 do not specify that the recess is beneath the pocket, but instead that the IMD is placed within the recess and the pocket. For example, the recess could be outside the pocket, and a portion of the IMD, such as one or more modules as stated in paragraph [0051], could be placed in the recess, while a different portion of the IMD could be placed in the pocket. Paragraph [0051] clearly provides written description support for placing all of an IMD or less than all of the IMD (e.g., one or more modules) within a recess. For this reason, the Examiner's statement that, "one of ordinary skill in the art would expect a recess to be formed in an exposed region of the skull (i.e. outside the claimed pocket),"[48] does not directly support the written description rejection of claims 12 and 27. The Examiner failed to provide any other substantive explanation as to why a person of ordinary skill in the art would not recognize in Appellant's disclosure a description of the invention of claims 12 and 27.

The Examiner failed to meet the initial burden of presenting by a preponderance of evidence why a person of ordinary skill in the art would not recognize in an Appellant's

[48] Final Office Action dated March 31, 2009, page 2.

disclosure a description of the invention defined by the claims.[49] The combination of using a pocket (as recited in independent claims 1 and 26) and a recess (as recited in claims 12 and 27) is clearly supported by Appellant's specification as filed. For these reasons, the Examiner's rejection of claims 12 and 27 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement is in error. Reversal of this rejection is requested.

SECOND GROUND OF REJECTION UNDER APPEAL

In the Office Action, the Examiner rejected claims 12 and 27 under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement. Appellant respectfully requests reversal of this rejection by the Board. Appellant's specification as filed meets the enablement requirement, as one skilled in the pertinent art at the time of Appellant's invention could have utilized the invention as recited in the claims without undue experimentation.

GROUP 2 - (Claims 12 and 27)

The combination of placing a device in a recess and a pocket is enabled by Appellant's specification as filed. A patent need not teach, and preferably omits, what is well known in the art.[50] For example, one of skill in the art would have understood that creation of a recess beneath a pocket could be accomplished using common surgical tools such as a bone chisel or a rotary bit. While Appellant does not agree that Appellant's specification as filed would not have enabled a recess beneath a pocket, Appellant again notes that claims 12 and 27 do not specify that the recess is beneath the pocket. For this reason, the Examiner's statement that, "since Applicant describes a spatula is used to create the pocket, it is unclear how a tool would be utilized to form a recess therein,"[51] does not support the enablement rejection of claims 12 and 27.

In the Advisory Action, the Examiner stated, "[f]urthermore, Applicant previously argued that language such as 'placing the IMD in a recess' supported the 'entire' device is placed..." The Examiner apparently contended that Appellant's previous arguments can be used to narrowly

[49] *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976).
[50] *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984).
[51] Final Office Action dated March 31, 2009, page 2.

construe, the feature of "placing the low-profile implantable medical device in the recess," as recited in claims 12 and 27, to mean placing the entire IMD in the recess. However, Appellant's previous arguments were related to the sentence, "The pocket may be opened sufficiently to receive IMD 12 or a portion thereof," as recited in paragraph [0022], to support the contention that the specification discloses placing all of IMD 12 in the pocket. As argued by the Appellant, in the context of "IMD 12 or a portion thereof," IMD 12 must refer to all of IMD 12; otherwise the phrase, "or a portion thereof" would have no meaning whatsoever. Such an argument is not applicable to the feature of, "placing the low-profile implantable medical device in the recess" as recited by claims 12 and 27, as these claims do not include the phrase "or a portion thereof." For this reason, the Examiner's narrow interpretation of the feature of "placing the low-profile implantable medical device in the recess," as to mean placing the entire low-profile implantable medical device in the recess is improper.

Claims 12 and 27 do not require placing the entire low-profile implantable medical device in the recess or in the pocket. Creation of a recess outside of a pocket is inarguably enabled by the specification as filed as one of skill in the art would clearly have understood that creation of a recess outside of a pocket could be accomplished using common surgical tools such as a bone chisel or a rotary bit. In addition, while not necessary to overcome the enablement rejection, one skilled in the art would also have understood that creation of a recess beneath a pocket could also be accomplished using common surgical tools such as a bone chisel or a rotary bit. For these reasons, claims 12 and 27 are enabled by the specification as filed.

Claims 12 and 27 recite subject matter included in the present application as originally filed and enabled by the present application as originally filed. For these reasons, the Examiner's rejection of claims 12 and 27 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement is in error. Reversal of this rejection is requested.

THIRD GROUND OF REJECTION UNDER APPEAL

In the Office Action, the Examiner rejected claims 1–7, 9–12, 15–17 and 24–32 under 35 U.S.C. § 103(a) as being unpatentable over Fischell in view of Berrang and Berrang Application. The cited references fail to teach each and every feature of the claimed invention. In addition, there is no rational reason why a person of ordinary skill in the art would have been

led to make a modification or combination to arrive at the claimed invention as required to properly maintain the rejection under 35 U.S.C. § 103(a).

GROUP 3 - (Claims 1-7, 9-11, 15, 17, 24 and 30)

Appellant's independent claim 1 is directed to a method comprising making an incision in a scalp of a head of a patient to create a scalp flap; separating the scalp flap from a skull of the patient, wherein the separated scalp flap is attached to the remainder of the scalp by a fold; after separating the scalp flap from the skull, separating a portion of the remainder of the scalp adjacent to the fold from the skull to create a pocket adjacent to the fold and between the scalp and the skull; placing at least a portion of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp; drilling one or more burr holes in a portion of the skull of the patient exposed by separating the scalp flap from the skull; and inserting one or more leads through the burr holes and into a brain of the patient.

In the rejection of independent claim 1, the Examiner cited Fischell as disclosing implanting a low profile medical device between the scalp and the cranium at the top of the head. The Examiner also found that Fischell discloses that the device may comprise a neurostimulator with brain leads, may be secured via bone screws, and may be implanted in a recess. The Examiner correctly found that Fischell fails to disclose implantation steps recited in Appellant's claims as well as specific dimensions of the device recited in Appellant's claims 2-6, but stated that the combined disclosures of Berrang and Berrang Application would have made such features obvious to one of ordinary skill in the art at the time of Appellant's invention.[52] The Examiner's analysis is error, as the Office Action fails to account for each of the features recited in the claims.

Claim 1 recites, in part, placing at least a portion of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp; drilling one or more burr holes in a portion of the skull of the patient exposed by separating the scalp flap from the skull; and inserting one or more leads through the burr holes and into a brain of the patient. The rejection failed to account for this combination features. For this reason alone, the Examiner failed to establish a *prima facie* case of obviousness with respect to claim 1.

[52] Final Office Action dated March 31, 2009, page 7.

In addition, the features recited in claim 1 would not have been obvious to one of ordinary skill in the art at the time of Appellant's invention. For example, neither Fischell, nor Berrang, nor Berrang Application teaches or suggests drilling a burr hole in a portion of a skull under a scalp flap that is also used to implant a low-profile medical device. In contrast, Fischell teaches wires are *tunneled under the scalp* to burr holes, e.g., as shown in FIGS. 15 and 16 and described in column 29, lines 21-48. In the Office Action, the Examiner characterized burr hole H1 as being not tunneled;[53] however, Appellant finds no support for such a characterization in Fischell as such a characterization contradicts the description in Fischell, column 29, lines 21-48. Appellant notes that wires 611, 616 are shown as being tunneled under the scalp at least some distance in Fischell, FIG. 15. Further, MPEP 2125 precludes relying upon proportions of features shown in a drawing absent evidence that the drawings are to scale. In this manner, the proportions shown in Fischell, FIG. 15 can not be used to overcome the description in Fischell, column 29, lines 21-48, which clearly teaches wires are tunneled under the scalp to burr holes.

Berrang and Berrang Application also fail to disclose the features of drilling one or more burr holes in a portion of the skull of the patient exposed by separating the scalp flap from the skull, and inserting one or more leads through the one or more burr holes and into the brain. Berrang and Berrang Application disclose techniques for a cochlear implant. The drilling disclosed by Berrang is used to implant a microphone in posterior wall of the external auditory canal of a patient.[54] The cochlear implants disclosed by Berrang and Berrang Application have no use for drilling a burr hole in the skull of a patient, much less for drilling a burr hole in a portion of the skull of the patient exposed by separating a scalp flap from the skull, and inserting a lead through the hole and into the brain.

Fischell, Berrang and Berrang Application also fail to disclose or suggest a pocket adjacent to the fold and between the scalp and the skull, or placing at least a portion of a low-profile implantable medical device in the pocket as recited by claim 1. In fact, neither Fischell, nor Berrang, nor Berrang Application demonstrates that there is any separation whatsoever between a scalp and skull behind as fold a recited in claim 1. The Office Action acknowledged

[53] Final Office Action dated March 31, 2009, page 3.
[54] Berrang, column 14, lines 52-59.

that Fischell fails to disclose implantation steps recited in Appellant's claims. Berrang and Berrang Application fail to provide a rational reason to create a pocket as recited in claim 1.

For example, in contrast to claim 1, Berrang illustrates in FIG. 3 that the implant is placed in front of the fold. Further, Berrang teaches that line 34 (FIG. 3) illustrates an incision whereby a surgeon raises a postauricular flap to facilitate the implantation.[55] Berrang teaches raising the postauricular flap, and placing the device beneath the flap, on the "flap" side of the fold. Berrang in no way suggests the additional step, after raising the flap, of creating a pocket adjacent to the fold and between the scalp and the skull. Because Berrang does not disclose creating a pocket, Berrang also does not disclose placing at least a portion of the low-profile implantable medical device in the pocket.

Similarly, Berrang Application also fails to teach or suggest such a feature. For example, as shown in FIG. 3 of Berrang Application, the implant is placed in front the fold. Further, Berrang Application teaches that skin flap 23 is pulled back to facilitate implantation.[56]

In the Advisory Action, the Examiner stated that Appellant's claims do not "preclude two steps from being achieved in a single step." Appellant disagrees as claim 1 clearly states that the pocket is created "after separating the scalp flap from the skull." The Examiner failed to account for this deficiency.

Because the Examiner failed to provide a rational reason one of ordinary skill in the art would have found the features of a pocket, placing at least a portion a low-profile implantable medical device in the pocket, drilling one or more burr holes in a portion of the skull of the patient exposed by separating the scalp flap from the skull, or inserting one or more leads through the one or more burr holes and into the brain as recited by claim 1, the Examiner failed to provide a *prima facie* case of obviousness as required to maintain the rejection under 35 U.S.C. §103(a). Likewise, the references also fail to support a rejection of dependent claims 2-7, 9-11, 15, 17, 24 and 30 under 35 U.S.C. § 103(a). For these reasons, the rejection of claims 1-7, 9-11, 15, 17, 24 and 30 is improper and should be reversed.

[55] Berrang, column 13, lines 40-53.
[56] Berrang Application, paragraph [0056].

GROUP 4 - (Claim 12)

Claim 12 is dependent on independent claim 1 and recites the additional features of creating a recess in the skull; and placing the low-profile implantable medical device in the recess. As discussed with respect to Group 3, *supra*, Fischell in view of Berrang and Berrang Application fails support a *prima facie* case of obviousness under 35 U.S.C. § 103 of claim 1. For example, the cited references fail to disclose the features of drilling one or more burr holes in a portion of the skull of the patient exposed by separating the scalp flap from the skull, and inserting one or more leads through the one or more burr holes and into the brain.

In addition, with respect to claim 12, the cited references fail to disclose creating a recess in the skull in combination with the features of claim 1, including the creation of a pocket adjacent to the fold and between the scalp and the skull. In the Office Action, the Examiner cited Fischell as disclosing forming a skull recess and placing a device therein.[57] However, Fischell instead discloses removing cranial bone to form a hole in the cranium.[58] Based on the ordinary meaning of the term "recess," a person of ordinary skill in the art would not have understood claim 12 to encompass forming a hole through the cranium. Furthermore, it would be clear to a person of ordinary skill in the art from the context of Appellant's specification as filed that the recess of claim 12 would not pass entirely through the cranium of a patient. As an example, Appellant's specification as filed does not include any discussion of the obvious complexities that exposing a portion of a patient's brain would entail. In this manner, Fischell fails to disclose creating a recess in the skull within the meaning of claim 12. Berrang and Berrang Application also fail to disclose such a feature.

The applied references fail to disclose the feature of creating a recess in the skull within the meaning of claim 12. For these reasons, the rejection of claim 12 under 35 U.S.C. § 103(a) is improper and should be reversed.

GROUP 5 - (Claim 16)

Claim 16 is dependent on independent claim 1 and recites the additional feature of adjusting the low-profile implantable medical device to cause a contour of the low-profile

[57] Final Office Action dated March 31, 2009, page 5.
[58] Fischell, abstract.

implantable medical device to more closely match a contour of the skull. As discussed with respect to Group 3, *supra*, Fischell in view of Berrang and Berrang Application fails support a *prima facie* case of obviousness under 35 U.S.C. § 103 of claim 1. For example, the cited references fail to disclose the features of drilling one or more burr holes in a portion of the skull of the patient exposed by separating the scalp flap from the skull, and inserting one or more leads through the one or more burr holes and into the brain.

In addition, with respect to claim 16, the cited references fail to disclose adjusting the low-profile implantable medical device to cause a contour of the low-profile implantable medical device to more closely match a contour of the skull. In the Office Action, the Examiner failed to provide any explanation whatsoever as how such a feature would have been obvious to one of ordinary skill in the art at the time of Appellant's invention. In addition, there is no rational reason such a feature would have been obvious to one of ordinary skill in the art at the time of Appellant's invention. In the event the Examiner fails to withdraw the rejection, Appellant respectfully requests the Examiner explain with specificity how one of ordinary skill in the art would have found such a feature to be obvious so that Appellant may have the opportunity to confront such an explanation, if any, in a reply brief.

The Examiner failed to make a *prima facie* case of obviousness with respect to claim 16. In addition, the combination of features provided by the invention as defined by claim 16 would not have been obvious to one of ordinary skill in the art at the time of Appellant's invention. For these reasons, the rejection of claim 16 under 35 U.S.C. § 103(a) is improper and should be reversed.

GROUP 6 - (Claim 25)

Claim 25 is dependent on independent claim 1 and recites the additional feature of placing all of the low-profile implantable medical device in the pocket. As discussed with respect to Group 3, *supra*, Fischell in view of Berrang and Berrang Application fails support a *prima facie* case of obviousness under 35 U.S.C. § 103 of claim 1. For example, the cited references fail to disclose the features of drilling one or more burr holes in a portion of the skull of the patient exposed by separating the scalp flap from the skull, and inserting one or more leads through the one or more burr holes and into the brain.

The Office Action failed to account for the feature of placing all of the low-profile implantable medical device in the pocket as recited by claim 25. In addition, there is no rational reason such a feature would have been obvious to one of ordinary skill in the art at the time of Appellant's invention. In the event the Examiner fails to withdraw the rejection, Appellant respectfully requests the Examiner explain with specificity how one of ordinary skill in the art would have found such a feature to be obvious so that Appellant may have the opportunity to confront such an explanation, if any, in a reply brief.

Appellant notes that the feature of placing all of the of the low-profile implantable medical device in the pocket as recited by claim 25 is supported both by paragraph [0022] as previously argued and by paragraph [0052]. For example, paragraph [0052] clearly states, "The surgeon may insert all or part of the IMD in the pocket and suture closed the incision." In addition, paragraph [0022] recites, "The pocket may be opened sufficiently to receive IMD 12 or a portion thereof." With respect to paragraph [0022], in the context of "IMD 12 or a portion thereof," IMD 12 must refer to all of IMD 12; otherwise the phrase, "or a portion thereof" would have no meaning whatsoever.

The Examiner failed to make a *prima facie* case of obviousness with respect to claim 25. In addition, the combination of features provided by the invention as defined by claim 25 would not have been obvious to one of ordinary skill in the art at the time of Appellant's invention. For these reasons, the rejection of claim 25 under 35 U.S.C. § 103(a) is improper and should be reversed.

GROUP 7 - (Claim 31)

Claim 31 is dependent on independent claim 1 and recites the additional feature of wherein the incision is a C-flap incision. As discussed with respect to Group 3, *supra*, Fischell in view of Berrang and Berrang Application fails support a *prima facie* case of obviousness under 35 U.S.C. § 103 of claim 1. For example, the cited references fail to disclose the features of drilling one or more burr holes in a portion of the skull of the patient exposed by separating the scalp flap from the skull, and inserting one or more leads through the one or more burr holes and into the brain.

In addition, with respect to claim 31, the cited references fail to disclose wherein the incision is a C-flap incision in combination with the features of claim 1, including the creation of a pocket adjacent to the fold and between the scalp and the skull. For example, the Office Action cites Berrang as disclosing a C-flap incision, but fails to provide any explanation whatsoever as to how it would have been obvious to one of ordinary skill in the art to provide a C-flap incision in combination with a pocket as recited in claim 1. The Examiner's rejection of claim 1 relies entirely upon embodiments in Berrang and Berrang Application that utilize an S-shaped incision. For example, the Examiner cited figure 3 of Berrang as disclosing the creation of a pocket.[59] In addition, the Examiner stated in the Advisory Action that the S-incision inherently creates a pocket. However, the arguments set forth by the Examiner regarding the creation of a pocket with respect to the S-shaped incision do not apply to a C-shaped incision, as a C-shaped incision would create a clear fold and flap.

The applied references fail to disclose the feature of wherein the incision is a C-flap incision in combination with the features of claim 1, including the creation of a pocket adjacent to the fold and between the scalp and the skull. For these reasons, the rejection of claim 31 under 35 U.S.C. § 103(a) is improper and should be reversed.

GROUP 8 - (Claim 26)

Appellant's independent claim 26 is directed to a method comprising: making an incision in a scalp at a top of a head of a patient to create a scalp flap at the top of the head of the patient; separating the scalp flap from a skull of the patient, wherein the separated scalp flap is attached to the remainder of the scalp by a fold; after separating the scalp flap from the skull, separating a portion of the remainder of the scalp adjacent to the fold from the skull to create a pocket adjacent to the fold and between the scalp and the skull; placing at least a portion of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp; drilling one or more burr holes in a portion of the skull of the patient exposed by separating the scalp flap from the skull; inserting one or more leads through the burr holes and into a brain of the patient; connecting the one or more leads to the low-profile implantable medical device; covering the

[59] Final Office Action dated March 31, 2009, page 7.

low-profile implantable medical device, leads and burr holes with the scalp flap; and closing the incision.

Independent claim 26 recites placing all of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp. As discussed with respect to claim 25 above, one of ordinary skill in the art would not have had a rational reason to include such a feature in the system disclosed by Fischell. For example, the Office Action failed to account for the feature of placing all of the low-profile implantable medical device in the pocket as recited by claim 25. In addition, there is no rational reason such a feature would have been obvious to one of ordinary skill in the art at the time of Appellant's invention. In the event the Examiner fails to withdraw the rejection, Appellant respectfully requests the Examiner explain with specificity how one of ordinary skill in the art would have found such a feature to be obvious so that Appellant may have the opportunity to confront such an explanation, if any, in a reply brief.

Because the Examiner failed to provide a rational reason one of ordinary skill in the art would have found the feature of placing all of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp as recited by independent claim 26, the Examiner failed to provide a *prima facie* case of obviousness as required to maintain the rejection under 35 U.S.C. §103(a). For these reasons, the rejection of claim 26 is improper and should be reversed.

GROUP 9- (Claim 27)

Claim 27 is dependent on independent claim 26 and recites the additional features of creating a recess in the skull; and placing the low-profile implantable medical device in the recess. As discussed with respect to Group 8, *supra*, Fischell in view of Berrang and Berrang Application fails support a *prima facie* case of obviousness under 35 U.S.C. § 103 of claim 1. For example, the cited references fail to disclose the feature of placing all of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp.

In addition, with respect to claim 27, the cited references fail to disclose creating a recess in the skull in combination with the features of claim 27, including the creation of a pocket adjacent to the fold and between the scalp and the skull. In the Office Action, the Examiner cited

Fischell as disclosing forming a skull recess and placing a device therein.[60] However, Fischell instead discloses removing cranial bone to form a hole in the cranium.[61] As is clear from the context of Appellant's specification as filed, the recess of claim 27 would not pass entirely through the cranium of a patient. As an example, Appellant's specification as filed does not include any discussion of the obvious complexities that exposing a portion of a patient's brain would entail. In this manner, Fischell fails to disclose creating a recess in the skull within the meaning of claim 27. Berrang and Berrang Application also fail to disclose such a feature.

The applied references fail to disclose the feature of creating a recess in the skull within the meaning of claim 27. For these reasons, the rejection of claim 27 under 35 U.S.C. § 103(a) is improper and should be reversed.

GROUP 10 – (Claims 28 and 32)

Appellant's independent claim 28 is directed to a method comprising: making an incision in a scalp at a top of a head of a patient to create a scalp flap at the top of the head of the patient; separating the scalp flap from a skull of the patient, wherein the separated scalp flap is attached to the remainder of the scalp by a fold; after separating the scalp flap from the skull, separating a portion of the remainder of the scalp adjacent to the fold from the skull to create a pocket adjacent to the fold and between the scalp and the skull; and placing at least a portion of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp.

Independent claim 28 includes the feature of placing at least a portion of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp. As discussed with respect to independent claim 1, one of ordinary skill in the art would not have had a rational reason to include such a feature in the system disclosed by Fischell.

For example, in contrast to claim 28, Berrang illustrates in FIG. 3 that the implant is placed in front of the fold. Further, Berrang teaches that line 34 (FIG. 3) illustrates an incision whereby a surgeon raises a postauricular flap to facilitate the implantation.[62] Berrang teaches raising the postauricular flap, and placing the device beneath the flap, on the "flap" side of the fold. Berrang in no way suggests the additional step, after raising the flap, of creating a pocket

[60] Final Office Action dated March 31, 2009, page 5.
[61] Fischell, abstract.
[62] Berrang, column 13, lines 40-53.

adjacent to the fold and between the scalp and the skull. Because Berrang does not disclose creating a pocket, Berrang also does not disclose placing at least a portion of the low-profile implantable medical device in the pocket.

Similarly, Berrang Application also fails to teach or suggest such a feature. For example, as shown in FIG. 3 of Berrang Application, the implant is placed in front of the fold. Further, Berrang Application teaches that skin flap 23 is pulled back to facilitate implantation.[63]

In the Advisory Action, the Examiner stated that Appellant's claims do not "preclude two steps from being achieved in a single step." Appellant disagrees as claim 28 clearly states that the pocket is created "after separating the scalp flap from the skull." The Examiner failed to account for this deficiency.

Because the Examiner failed to provide a rational reason one of ordinary skill in the art would have found the features of a pocket, and placing at least a portion a low-profile implantable medical device in the pocket as recited by claim 28, the Examiner failed to provide a *prima facie* case of obviousness as required to maintain the rejection under 35 U.S.C. §103(a). Likewise, the references also fail to support a rejection of dependent claim 32 under 35 U.S.C. § 103(a). For these reasons, the rejection of claims 28 and 32 is improper and should be reversed.

GROUP 11 – (Claim 29)

Claim 29 is dependent on independent claim 28 and recites the additional feature of placing all of the low-profile implantable medical device in the pocket. As discussed with respect to Group 3, *supra*, Fischell in view of Berrang and Berrang Application fails support a *prima facie* case of obviousness under 35 U.S.C. § 103 of claim 28. For example, the cited references fail to disclose the features of a pocket, and placing at least a portion a low-profile implantable medical device in the pocket within the context of claim 28.

The Office Action failed to account for the feature of placing all of the low-profile implantable medical device in the pocket as recited by claim 29. In addition, there is no rational reason such a feature would have been obvious to one of ordinary skill in the art at the time of Appellant's invention. In the event the Examiner fails to withdraw the rejection, Appellant

[63] Berrang Application, paragraph [0056].

respectfully requests the Examiner explain with specificity how one of ordinary skill in the art would have found such a feature to be obvious so that Appellant may have the opportunity to confront such an explanation, if any, in a reply brief.

The Examiner failed to make a *prima facie* case of obviousness with respect to claim 29. In addition, the combination of features provided by the invention as defined by claim 29 would not have been obvious to one of ordinary skill in the art at the time of Appellant's invention. For these reasons, the rejection of claim 29 under 35 U.S.C. § 103(a) is improper and should be reversed.

CONCLUSION OF ARGUMENT

All claims in this application are in condition for allowance. In view of Appellant's arguments, Appellant respectfully requests the Board promptly withdraw each of the rejections and place the application in condition for immediate allowance. Appellant respectfully requests separate review by the Board for each of the groups addressed above under separate headings.

Respectfully submitted,

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CLAIMS APPENDIX

1. A method comprising:

making an incision in a scalp of a head of a patient to create a scalp flap;

separating the scalp flap from a skull of the patient, wherein the separated scalp flap is attached to the remainder of the scalp by a fold;

after separating the scalp flap from the skull, separating a portion of the remainder of the scalp adjacent to the fold from the skull to create a pocket adjacent to the fold and between the scalp and the skull;

placing at least a portion of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp;

drilling one or more burr holes in a portion of the skull of the patient exposed by separating the scalp flap from the skull; and

inserting one or more leads through the burr holes and into a brain of the patient.

2. The method of claim 1, wherein the low-profile implantable medical device comprises:

a first module that includes control electronics within a first housing;

a second module that includes a second housing; and

a flexible overmold that at least partially covers the first and second housings.

3. The method of claim 1, wherein the low-profile implantable medical device has a maximum thickness of between approximately 4 millimeters and approximately 8 millimeters.

4. The method of claim 1, wherein the low-profile implantable medical device has a maximum thickness of approximately 6 millimeters.

5. The method of claim 1, wherein the low-profile implantable medical device has a periphery and wherein the angle between the periphery and the skull is greater than ninety degrees.

6. The method of claim 5, wherein the angle is approximately 135 degrees.

7. The method of claim 1, further comprising connecting the one or more leads to the low-profile implantable medical device.

9. The method of claim 1, further comprising anchoring the low-profile implantable medical device to the skull.

10. The method of claim 9, wherein anchoring the low-profile implantable medical device to the skull comprises anchoring the low-profile implantable medical device to the skull with a bone screw.

11. The method of claim 1, further comprising:

covering an exposed portion of the low-profile implantable medical device with the scalp flap; and

suturing the scalp flap to close the incision.

12. The method of claim 1, further comprising:

creating a recess in the skull; and

placing the low-profile implantable medical device in the recess.

15. The method of claim 1, wherein the low-profile implantable medical device is contoured in three dimensions to substantially conform to the shape of a skull.

16. The method of claim 1, further comprising adjusting the low-profile implantable medical device to cause a contour of the low-profile implantable medical device to more closely match a contour of the skull.

17. The method of claim 1, further comprising administering a local anesthetic to the patient prior to making the incision.

24. The method of claim 1, wherein the incision is made in a top of the head of the patient.

25. The method of claim 1, wherein placing at least a portion of the low-profile implantable medical device in the pocket comprises placing all of the low-profile implantable medical device in the pocket.

26. A method comprising:

making an incision in a scalp at a top of a head of a patient to create a scalp flap at the top of the head of the patient;

separating the scalp flap from a skull of the patient, wherein the separated scalp flap is attached to the remainder of the scalp by a fold;

after separating the scalp flap from the skull, separating a portion of the remainder of the scalp adjacent to the fold from the skull to create a pocket adjacent to the fold and between the scalp and the skull;

placing at least a portion of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp;

drilling one or more burr holes in a portion of the skull of the patient exposed by separating the scalp flap from the skull;

inserting one or more leads through the burr holes and into a brain of the patient;

connecting the one or more leads to the low-profile implantable medical device;

covering the low-profile implantable medical device, leads and burr holes with the scalp flap; and

closing the incision.

27. The method of claim 26, further comprising:

creating a recess in the skull; and

placing the low-profile implantable medical device within the recess.

28. A method comprising:

making an incision in a scalp at a top of a head of a patient to create a scalp flap at the top of the head of the patient;

separating the scalp flap from a skull of the patient, wherein the separated scalp flap is attached to the remainder of the scalp by a fold;

after separating the scalp flap from the skull, separating a portion of the remainder of the scalp adjacent to the fold from the skull to create a pocket adjacent to the fold and between the scalp and the skull; and

placing at least a portion of a low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp.

29. The method of claim 28, wherein placing the portion of the low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp comprises placing all of the low-profile implantable medical device in the pocket adjacent to the fold and underneath the scalp.

30. The method of claim 1, wherein the low-profile implantable medical device is a neurostimulator that provides deep brain stimulation.

31. The method of claim 1, wherein the incision is a C-flap incision.

32. The method of claim 28, wherein the low-profile implantable medical device is a neurostimulator that provides deep brain stimulation.

EVIDENCE APPENDIX

NONE

RELATED PROCEEDINGS APPENDIX

NONE